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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,169	04/06/2004	John L. Faul	S03-013/US	7036

30869 7590 09/27/2006

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No.	Applicant(s)	
	10/820,169	FAUL ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101/112

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4, 6, and 8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well - established utility.

With regard to claims 4, 6, and 8, applicant attempts to claim that the recited method increases O_2 concentration in the patient's blood, increases cardiac output, and decreases a particular vessel's blood pressure. However, applicant fails to set forth any evidence that such an increase is provided by the method. Applicant's specification (see US 2004/0249335 at paragraph 0037-0039) merely provides that such a shunting treatment *may* increase a patient's O_2 concentration, cardiac output, or decrease a particular vessel's blood pressure.

Claims 4, 6, and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Objections

4. Claims 1-11 are objected to as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claim 1, Applicant attempts to claim a therapeutic method by decreasing the systemic vascular resistance of a patient by providing a shunt, but never actually claims the step of implanting the shunt within the patient. Applicant merely claims "having...an implantable arteriovenous shunt" in a particular location, subsequently referring to "said implantation." Such a recitation is insufficient to amount to a claim of implantation. For the purposes of examination on the merits and in the interest of compact prosecution, Examiner has assumed that the method claimed by applicant includes the step of implanting the claimed shunt.

In claims 3, 5, and 7, applicant attempts to further define a method, but fails to set forth any additional steps in the method. For the purposes of examination, Examiner interprets the claims to indicate that the claimed method may be used to treat a respiratory, cardiac, or circulatory condition.

Appropriate correction is required.

5. Claim 17 is objected to because it recites the limitation "the radius" in line 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required. For the purposes of examination, Examiner has interpreted "the radius" to comprise the internal radius of the claimed shunt device.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/961,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because, despite some variance in claim terminology, each substantive element or method step contained in the instant claims are present in the claims of the copending case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-11, 13-15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,662,711 to Douglas.

In the specification and figures, Douglas discloses the method substantially as claimed by applicant. With regard to claims 1, 9, 18, as interpreted by the examiner (see claim objection above), Douglas discloses a method of reducing a patient's vascular resistance by using a resistor 110 to control fluid flow through a shunt 100 implanted between the pulmonary artery and another systemic blood vessel, which may be a vein (see FIG 2, column 1, lines 65-67, column 2, lines 1-20).

With regard to applicant's claim limitations (e.g., claim 1) drawn to the flow rate of fluid through the shunt, Douglas specifically discloses that the shunt 100 includes an adjustable restrictor or valve 110 that is used to adjust the flow rate of blood through the shunt to control the oxygen saturation level of the blood flowing through the shunt (see column 2, lines 11-28, column 4, lines 19-25). The flow rate is controlled by adjusting the cross-sectional area of the shunt via bladder 113 (see column 2, lines 29-38). Douglas specifically teaches that the rate of flow through the shunt is a result-effective variable that may be used to achieve the desired oxygen saturation level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the rate of flow through the Douglas shunt to the rate claimed by applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05. In this case, a person of ordinary skill in the art would reasonably obtain applicant's flow rate by optimizing the flow rate in the manner taught by Douglas (column 2, lines 29-38).

With regard to applicant's claims (eg, claims 13, 15) drawn to the cross-sectional area of the shunt, Douglas specifically The flow rate is controlled by adjusting the cross-sectional area of the shunt via bladder 113 (see column 2, lines 29-38). Douglas specifically teaches that the rate of flow through the shunt is a result-effective variable that may be used to achieve the desired oxygen saturation level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the rate of flow through the Douglas shunt to the rate claimed by applicant, since

it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05. In this case, a person of ordinary skill in the art would reasonably obtain applicant's flow rate by optimizing the flow rate in the manner taught by Douglas (column 2, lines 29-38).

With regard to claims 3, 5, and 7, Douglas discloses that the method may be used to convey blood from the aorta to the pulmonary system to oxygenate the blood, thereby providing a respiratory therapy (see column 1, lines 24-35) Similarly, Douglas discloses that the method may treat congenital heart defects (see column 1, lines 4-6), thereby providing cardiac therapy. Douglas further discloses that the method may reduce vascular resistance (see column 2, lines 1-3), thereby providing circulatory therapy.

With regard to claims 4, 6, and 8, applicant fails to disclose that his method is actually capable of providing the claimed benefits. It is the position of the Examiner that since the shunt and method disclosed by applicant satisfy the limitations of Applicant's claims, the Douglas shunt and method are capable of producing the results claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 10 and 19, Douglas discloses that the restrictor 110 in shunt 100 may be selectively activated by controller 120 to control fluid flow rate through the shunt based on signals from sensor 114 that monitors oxygen saturation, meeting the limitations of the claim (see column 2, lines 11-28, column 4, lines 19-25). With regard to applicant's claim 19 drawn to the operation of the sensor, such a

limitation is considered by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Douglas discloses that the device comprises a sensor 114, but does not disclose that the sensor is "to sense" rate or pressure. However, Douglas discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see column 5, lines 35-50). Therefore, Douglas discloses that the device is *capable* of operating as claimed by applicant (i.e., in response to rate or pressure), meeting the limitations of the claim.

With regard to claim 11, Douglas discloses that the controller 120 is capable of controlling the restriction of the shunt 100 via bladder 130, which adjusts the cross-sectional area of the shunt (see column 4, lines 19-59). Douglas does not disclose that the controller controls the bladder as a function of the pressure difference across the shunt. However, Applicant merely claims that the device is *capable* of performing such a procedure as a function of pressure. Douglas discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see column 5, lines 35-50). Therefore, Douglas discloses that the device is *capable* of operating as claimed by applicant (i.e., in response to rate or pressure), meeting the limitations of the claim.

With regard to claim 14, and its recitation of the site of implantation of the claimed device, Examiner considers such limitations to be a statement of the intended

use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Douglas discloses that the shunt may be implanted between the aorta and another systemic blood vessel (see column 2, lines 11-15), indicating that the device may be implanted in applicant's claimed location, meeting the limitations of the claim.

With regard to claim 20, Douglas discloses that the shunt device 100 comprises a restrictor 110 connected to controller 120 that uses bladder 113 as a flow control element to control flow through the shunt (see column 2, lines 11-38).

With regard to applicant's claim 21 drawn to the automatic, self-adjusting operation of the shunt, such limitations are considered by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Douglas discloses that the controller 120 is capable of controlling the restriction of the shunt 100 via bladder 130, which adjusts the cross-sectional area of the shunt (see column 4, lines 19-59). Furthermore, Douglas discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see column 5, lines 35-50). Therefore, Douglas discloses that the device is *capable* of

operating as claimed by applicant (i.e., automatically), meeting the limitations of the claim.

10. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 5,895,404 to Ruiz.

In the specification and figures, Douglas discloses the device substantially as claimed by applicant (see rejection above) with the exception of using a specific implantation procedure and implanting the shunt between the aorta and the inferior vena cava.

With regard to claim 2, Ruiz discloses a method of treating a patient in need of cardiac therapy by percutaneously forming a passage between the aorta and the superior vena cava in order to treat complex single ventricle anatomy (see column 1, lines 47-65).

Absent a disclosure by applicant that connection to the inferior vena cava produces an unexpected or beneficial result over connection to the superior vena cava, it is the position of the Examiner that connection to the vena cava, which is a contiguous blood vessel, in either the superior location or inferior location would be sufficient to provide therapeutic benefits as disclosed by Ruiz. See MPEP 2144.03. Applicant has not disclosed that the placement in the inferior vena cava solves any stated problem or is for any particular purpose, and it appears that the method would perform equally well with implantation in either the inferior or superior vena cava, as disclosed by Ruiz.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to implant a shunt as disclosed by Douglas between

the aorta and vena cava, as disclosed by Ruiz, in order to treat complex single ventricle anatomy conditions, as taught by Ruiz (column 1, lines 47-65).

With regard to claim 12 drawn to the method of implantation, Ruiz specifically discloses an intravascular implantation procedure that minimizes trauma to the patient and recuperation time (see column 1, lines 48-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use a minimially invasive intravascular implantation procedure as disclosed by Ruiz to implant the shunt disclosed by Douglas in order to minimize patient trauma, as taught by Ruiz.

11. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 6,569,128 to Christensen et al.

In the specification and figures, Douglas discloses the device substantially as claimed by applicant (see rejection above) with the exception of the claimed length and radius of the shunt. It is well-known in the art of fluid dynamics that changes in the length or diameter (and accordingly, the radius) of tubing will affect the flow rate of fluid flowing through the tube. For example, Christensen discloses a shunt with a flow restrictor wherein variation of the length of the tube and the internal diameter (which is merely twice the radius of the tube) affects the flow rate according to Poiseuille's Law concerning fluid dynamics (see column 3, lines 65-67, column 4, lines 1-18).

Douglas discloses that precise control of blood flow through the disclosed shunt may ameliorate the side effects of certain conditions associated with increased vascular resistance. Douglas suggests the desirability of precise control of flow rate as a variable that may be optimized to control side effects, and Poiseuille's Law demonstrates the

ability to control flow rate via manipulation of tube length and diameter (and therefore radius).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05. In the instant case, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the length and radius of the tubing disclosed by Douglas, since Christensen and Poiseuille's Law demonstrate that such manipulation will affect flow rate through a tube, optimizing Douglas's result-effective variable.

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 5,867,718 to Fischer et al.

In the specification and figures, Douglas discloses the device substantially as claimed by applicant with the exception of a coating to prevent clot formation. Fischer discloses an arterio-venous shunt that has an internal coating such as heparin to prevent thrombus, or clot formation (see column 6, lines 39-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt disclosed by Douglas with a coating such as heparin, as disclosed by Fischer, in order to prevent thrombus or clot formation, as taught by Fischer.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 6,827,698 Kleinekofort

i. Method of determining blood flow rate through an arteriovenous shunt using pressure and flow measurements

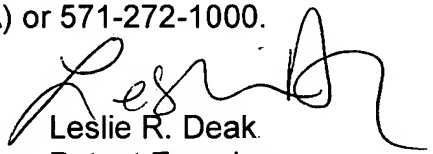
b. US 2005/0277967 A1 Brenneman et al

ii. Method of providing oxygenated blood to systemic circulation via a shunt

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
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Art Unit 3761
11 September 2006